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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,452	05/04/2001	Michael Lassner	02-104910US	8657

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MAXYGEN, INC.
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EXAMINER

LAMBERTSON, DAVID A

ART UNIT	PAPER NUMBER
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1636

14

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/849,452

Applicant(s)

LASSNER ET AL.

Examin r

David A. Lambertson

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 94-104 and 129-132 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 94,98,100-103,129 and 130 is/are rejected.
- 7) ☒ Claim(s) 95-97,99,104,131 and 132 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of a reply, filed May 16, 2003 as Paper No. 13, to the previous Office Action. Amendments were made to the claims. Specifically, claims 1-93 and 105-128 were cancelled, and claims 94-104 and 129-132 were amended.

Claims 94-104 and 129-132 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, Paper No. 11, mailed November 19, 2002, that is not addressed in this action has been withdrawn.

Information Disclosure Statement

Applicant has supplied the missing references from the previous IDS, Paper No. 6. A second copy of the previous form PTO-1449 has been placed in the file indicating that these references have been considered. The references that had previously been considered have been crossed out to avoid duplicate references being cited. A second copy of the previous form PTO-1449 has been signed and initialed at the appropriate references, and has been attached to this Office Action for applicant's records.

Specification

The disclosure is objected to because of the following informalities: the Brief Description of the Figure is insufficient as there are abbreviations in the figure that are not clearly indicated in the brief description of the figure. The brief description must clearly indicate the meaning of

Art Unit: 1636

each of the abbreviations so that the figure can be reasonably understood. The abbreviations that require description include: RdRp, sg pro, 25, 12, 8, CP, gene A', gene A'' and gene A'''.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 100 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 100 is unclear as to what is meant by a "PR promoter" because the acronym is not clearly defined upon the first appearance of the acronym PR. It would be remedial to clearly indicate the meaning of PR, similarly to the manner in which SAR was described. **This is a new rejection that is not necessitated by amendment.**

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 94, 100-103, 129 and 130 are rejected under 35 U.S.C. 102(b) as being anticipated by Pontier *et al.*, 1998 (*Molecular Plant-Microbe Int.* 11:544-554, 1998; see entire

Art Unit: 1636

document; henceforth Pontier 1998). **This is a new rejection that is not necessitated by amendment.**

Pontier 1998 describes the use of transgenic tobacco lines containing the *hsrJ203* promoter fused to the GUS reporter gene, and the ability of these transgenic lines to express the GUS reporter gene when confronted with pathogens such as *R. solanacearum*, *P. syringae* and *E. amylovora* (see for example page 545-546, the paragraph bridging the pages). Pontier 1998 also describes these cells where they express the R gene *N* (see for example page 546, bottom of the first incomplete paragraph), which is identified in Table 1 of the specification as a representative R gene (see for example page 14 of the instant specification). Furthermore, since the GUS reporter is induced with respect to the pathogens, the cell must contain a responsive R gene, otherwise the response would not be activated and the GUS reporter would not be expressed. By this rationale, Pontier 1998 anticipates claim 94 and 101. Since the GUS reporter gene was induced in response to these pathogens, the *hsrJ203* promoter can be characterized as a “PR promoter”, wherein “PR promoter” represents a pathogenesis-related promoter, as indicated in the specification (see for example page 11, lines 20-29 of the instant specification), and thereby anticipating claim 100. The reporter component is present on plasmid pHG21, which is an extrachromosomally replicating plasmid (see for example page 545, last sentence of the paragraph, in reference to the construct described Pontier 1994, supplied herewith), thereby anticipating claim 103. Because the pathogens used in this assay are known to cause the lethal wilting of tobacco and are known to produce the hairpin elicitor (an *hrp* gene product), these pathogens produce an elicitor that is a component of a crop pathogen thereby anticipating claims 129 and 130.

Art Unit: 1636

Pontier 1998 further describes the use of a tomato plant system expressing the *Lehsr203* gene (tomato homolog of *hsrJ203*) and Cf9, another exemplified R gene (see for example page 14 of the instant specification). In this instance, the reporter is the *Lehsr203* gene itself, which is detected by Northern analysis (see for example page 546, last two paragraphs) as a result of its expression in response to the Cf9 elicitor, AVR9 (a corresponding AVR gene). It is noted that a reporter, as commonly defined, need only be something that is detectable in a response to some event. Therefore, Pontier 1998 again anticipates claims 94 and 101. In addition, the *Lehsr203* gene in this instance is the chromosomal copy of the gene, and is therefore stably within the chromosome of the plant cell, thus anticipating claim 103.

Claims 94, 100, 101, 103, 129 and 130 are rejected under 35 U.S.C. 102(b) as being anticipated by Pointer *et al.* 1994 (*Plant J.* 5:507-521, 1994; see entire document; henceforth Pontier 1994). **This is a new rejection that is not necessitated by amendment.**

Pontier 1994 describes the use of transgenic tobacco lines containing the *hsrJ203* promoter fused to the GUS reporter gene, and the ability of these transgenic lines to express the GUS reporter gene when confronted with the pathogen *P. solanacearum* (see for example page 509, the paragraph bridging the left and right columns). Since the GUS reporter is induced with respect to the pathogens, the cell must contain a responsive R gene, otherwise the response would not be activated and the GUS reporter would not be expressed. The reporter construct is expressed on plasmid pHG21, thereby representing an extrachromosomally replicating bio-detector. As a result, Pontier 1994 anticipates claims 94, 101 and 103. Furthermore, the activation of the *hsrJ203* promoter occurs in response to a pathogen, therefore the promoter can

Art Unit: 1636

be characterized as a pathogen-related promoter, or "PR" promoter, as indicated in claim 100.

Significantly, the pathogen that is used causes the lethal wilting of different plant species, due to the production of an elicitor called hairpin (see for example page 508, first full paragraph), therefore the elicitor represents a component and a product of a crop pathogen. Therefore, Pontier 1994 also anticipates claims 129 and 130.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 98 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pontier 1998 as applied to claims 94, 100-103, 129 and 130, in further view of Hasselof *et al.* (US 6,255,558; see entire document; henceforth Hasselof). **This is a new rejection that is not necessitated by amendment.**

Pontier 1998 anticipates the claims as set forth above in the rejection under 35 USC 102(b). Pontier 1998 does not specifically teach the use of GFP or a luciferase as a reporter.

Hasselof teaches the use of several reporters to detect expression from a given promoter sequence, wherein these reporters are preferably GFP, GUS or a luciferase (see for example column 3, lines 41-44).

It would have been obvious for one of ordinary skill in the art to substitute GFP or a luciferase as the reporter because Hasselof clearly teaches that these reporters are useful in

Art Unit: 1636

detecting the activation of a promoter sequence. The ordinary skilled artisan would have been motivated to combine these teachings in order to use a preferred reporter sequence for the purpose of detecting the activation of a promoter sequence, as suggested by Hasselof as it regards the use of GFP, GUS and luciferase. Absent evidence to the contrary, the ordinary skilled artisan would have had a reasonable expectation of success when combining the teachings of Pointer 1998 and Hasselof.

Claim 98 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pontier 1998 as applied to claims 94, 100-103, 129 and 130, in further view of Hasselof *et al.* (US 6,255,558; see entire document; henceforth Hasselof). **This is a new rejection that is not necessitated by amendment.**

Pontier 1994 anticipates the claims as set forth above in the rejection under 35 USC 102(b). Pontier 1994 does not specifically teach the use of GFP or a luciferase as a reporter.

Hasselof teaches the use of several reporters to detect expression from a given promoter sequence, wherein these reporters are preferably GFP, GUS or a luciferase (see for example column 3, lines 41-44).

It would have been obvious for one of ordinary skill in the art to substitute GFP or a luciferase as the reporter because Hasselof clearly teaches that these reporters are useful in detecting the activation of a promoter sequence. The ordinary skilled artisan would have been motivated to combine these teachings in order to use a preferred reporter sequence for the purpose of detecting the activation of a promoter sequence, as suggested by Hasselof as it regards the use of GFP, GUS and luciferase. Absent evidence to the contrary, the ordinary

Art Unit: 1636

skilled artisan would have had a reasonable expectation of success when combining the teachings of Pointer 1994 and Hasselof.

Allowable Subject Matter

Claims 95-97, 99, 104, 131 and 132 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson
July 25, 2003

DAVID GUZO
PRIMARY EXAMINER
